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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/685,953	10/15/2003	Kevin J. Rozeboom	066379-9001-02	7946

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EXAMINER	
AFREMOVA, VERA	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 03/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/685,953	ROZEBOOM ET AL.	
	Examiner	Art Unit	
	Vera Afremova	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34-46 and 50-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34-46 and 50-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/15/03;10/18/04;* 12/19/05; 9/07/04

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application (PTO-152)

6)☐ Other: _____.

DETAILED ACTION

Claims 34-46 and 50-52 (preliminary amendment 10/15/2003) are pending and under examination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 34-40 and 44-46 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,150,163 (McPerson et al) (IDS reference).

Claims are directed to an animal cell culture medium composition comprising at least one activated growth factor selected from the group consisting of insulin-like growth factor (IGF) and transforming growth factor (TGF). Some claims are further drawn to the use of TGF beta 1 or TGF beta 2 in the cell culture medium. Some claims are further drawn to the use of IGF-1 in the cell culture medium. Some claims are further drawn to the use of activated growth factor preparation comprising at least about 75% or at least about 90% unbound growth factor.

US 6,150,163 discloses a cell culture medium composition comprising combination of growth factors TGF beta and IGF (abstract or col. 29, lines 37-39). The medium supplemented with growth factors is found to be biologically functional and biologically active as disclosed and, thus, the growth factors are reasonably expected to be in unbound form or in fully activated form within the meaning of the claims. Accordingly to the applicants' generic definitions an "activated" factor means a factor that is unbound to proteins (page 4, par. 00016). The definitions

are generic with regard to bounding proteins and, thus, the definitions encompass the use of pure or purified growth factor preparations. It is known that chemical reagents or preparations of TGF and IGF are made in 95-99% purified form (unbound or not bound to contaminating or carrier proteins) as evidenced by US 5,864,021 (col. 9, lines 11-20 and col.11, lines 45-47) and by US 5,231,178 (abstract). Thus, the growth factors in the cited medium composition of US 6,150,163 are pure, unbound or activated growth factors within the meaning of the claims when read in the light of instant specification.

2. Claims 34-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Naz et al. (IDS reference; Journal of Cellular Physiology. 1991, 146:156-163).

Claims are directed to a cell culture medium for reproductive cell comprising at least one activated growth factor such as TGF beta 1. Some claims are further drawn to the use of activated growth factor preparation comprising at least about 75% or at least about 90% unbound growth factor.

The reference by Naz et al discloses a cell culture medium for sperm cells that comprises medium Ham's F-10 (page 157, col. 1, par. 2, line 6) and growth factor TGF beta or TGF beta-1 at concentration 5-50 ng/ml or 5000-50000 ng/L (see tables 1 and 2). TGF beta-1 is a purified preparation. The medium supplemented with growth factor is found to be biologically functional as related to reproductive or sperm cells. Thus, the growth factor is reasonably expected to be in unbound form or in fully activated form within the meaning of the claims. Therefore, the cited reference anticipates the claimed invention.

3. Claims 34 and 44-46 are rejected under 35 U.S.C. 102(b) as being by Lackey et al. (IDS reference; Archives or Andrology. 1998, 41:115-125).

Claims are directed to a cell culture medium for reproductive cell comprising at least one activated growth factor such as insulin like growth factor (IGF-1). Some claims are further drawn to the use of activated growth factor preparation comprising at least about 75% or at least about 90% unbound growth factor.

The reference by Lackey et al discloses a cell culture medium for sperm cells that comprises a balanced salt buffer MTM or Tyrodes' medium and growth factor IGF-1 at concentration 100 ng/mL (abstract page 117). IGF is a purified preparation. The medium supplemented with growth factor is found to be biologically functional as related to reproductive or sperm cells. Thus, the growth factor is reasonably expected to be in unbound form or in fully activated form within the meaning of the claims. Therefore, the cited reference anticipates the claimed invention.

4. Claims 34-46 and 50-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Nocera et al. (IDS references; AJRI. 1995, 33:282-291).

Claims are directed to a culture medium composition comprising activated growth factors TGF beta 1, TGF beta 2 and IGF-1. Some claims are further drawn to the use of activated growth factor preparation comprising at least about 75% or at least about 90% unbound growth factor.

The reference by Nocera et al. teaches that seminal plasma contains growth factors in activated and latent from and that activation of latent forms is achieved by acid pH (abstract). In particular, the reference by Nocera et al. teaches presence of TGF beta 1 and TGF beta 2 in

seminal plasma (abstract and table 1). The seminal plasma also contains IGF-1 as evidenced by Lackey et al. (page 116, par. 1-3). Thus, the acidified seminal plasma samples disclosed by Nocera et al. is a composition comprising all 3 factors TGF beta 1, TGF beta 2 and IGF-1 in activated form or 100% unbound. The acidified seminal plasma is a medium physiologically suitable for sperm cells and it protects immunologically protect the integrity of sperm as taught by Nocera et al.(abstract, last lines). Therefore, the cited reference anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 34-46 and 50-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,150,163 (McPerson et al).

Claims as explained above. Some claims are further drawn to incorporation of all three growth factors TGF beta 1, TGF beta 2 and IGF-1 into the cell culture medium.

The cited patent US 6,150,163 is relied upon as explained above. Although the complete defined cell culture medium of the cited patent US 6,150,163 includes combination of two growth factors IGF-1 and either TGF beta 1 or TGF beta 2, the cited patent teaches that TGF beta 1 and TGF beta 2 are equivalents and that they have similar properties and produce the same effects in animal cell culture medium (example 8).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to combine all three growth factors including IGF-1, TGF beta 1 and TGF beta 2 in an animal cell culture medium with a reasonable expectation of success in culturing animal cells because the prior art teaches combination of IFG-1 and TGF beta in one culture medium composition wherein TGF beta 1 and beta 2 are equivalents in the animal cell culture medium as taught and suggested by the prior art. Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary. It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

2. Claims 34-46 and 50-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over the reference by Naz et al. and the reference by Lackey et al. taken with reference by Nocera et al.

The references by Naz et al. and by Lackey et al. are relied upon as explained above for the disclosure of animal sperm cell culture media with at least one purified or activated growth factor TGF beta or IGF-1. In particular, the reference by Naz et al. teaches incorporation of

growth factor TGF beta 1 into sperm cell culture medium but it is silent with regard to growth factor IGF. However, the reference by Lackey et al teaches incorporation of IGF-1 into animal sperm cell culture medium. The reference by Lackey et al also teaches that growth factors including IGF are present in animal seminal plasma and these factors provide for a natural environment for animal sperm cells. In addition, the reference by Nocera et al. teaches that other growth factors including TGF beta 1 and TGF beta 2 are also within animal seminal plasma and they activated in acidic environment.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to combine growth factors including IGF-1, TGF beta 1 and TGF beta 2 in an animal sperm cell culture medium with a reasonable expectation of success in providing a physiologically suitable medium or environment for sperm cells because the physiologically suitable conditions provided by seminal plasma include growth factors that are presently claimed and because the prior art teaches incorporation of growth factors TGF beta and IGF into artificial cell culture media intended for sperm cells. Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary. It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). Further, one of skill in the art would have been motivated to use activated, unbound or

pure preparations of growth factors for the expected benefits in providing biologically functional culture medium environment. The concept of using "activated" factors is generic as claimed and when read in the light of specification.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

AU 1651

March 16, 2006

VERA AFREMOVA

PRIMARY EXAMINER